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VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER

BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,986

Applicant(s)

ERAMO, LINCOLN

Examiner

/Susan W. Berman/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 63-73 is/are pending in the application.
- 4a) Of the above claim(s) 14, 18-20, 38, 44-61, 63-70 and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-17, 21-37, 39-43 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 and 63-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Election/Restrictions

Newly submitted claims 28-43, 72, 59-61, 63-70 and 73 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Invention I, claims 1-41, 71 and 72, drawn to an uncured and a cured composition, classified in class 522, subclass various depending on the hydrophilic polymer.

Invention II, claims 44-58, drawn to a method of coating a substrate, classified in class 427, subclass 508.

Invention III, claims 42, 43, 59-61, 63-70 and 73, drawn to a catheter assembly, classified in class 623, subclass .

Inventions I and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a composition for coating a substrate other than a medical device or a composition for providing a catheter assembly and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of making can be used to make a coated substrate other than a catheter assembly, such as a lens or in a drug delivery system.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-61, 63-70 and 73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 44-58, drawn to a method of coating, may be rejoined upon finding allowable subject matter in the compositions claims and amendment of the method claims to be of the same scope as any allowable composition claims. The claims drawn to a non-elected species will be considered upon finding an allowable claim generic to the elected and non-elected species.

Response to Amendment

The objection to claims 13, 28, 37 and 59-61 because of informalities is withdrawn.

The rejection of claims 13, 29, 30, 37, 42, 43, and 59-70 under 35 U.S.C. 112, second paragraph, is withdrawn.

Response to Arguments

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Burns et al (6,506,823) is withdrawn. Applicant argues that Burns et al are silent with respect to the disclosed compositions providing lubricity to a substrate and with respect to the disclosed polymerizable reactive diluents having glass transition temperatures both above and below 25⁰C and the disclosed acrylated urethane providing lubricity to the substrate. Applicant argues that the disclosed nitrocellulose is not hydrophilic and would not provide lubricity when wet to a surface and provided a data sheet for Nitrocellulose (less than 12.6% nitrogen) to support these

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arguments. It is agreed, upon reconsideration, that Burns et al do not disclose a lubricious composition comprising that provides lubricity when wet. Burns et al disclose compositions for providing protective hard coatings on wood type substrates.

The rejection of claims as being unpatentable over Buscemi et al (5,693,034) in combination with Burns et al (6,506,823) is withdrawn for the reasons set forth above.

The rejection of claims as being unpatentable over Burns et al (6,506,823 in view of Bae et al (5,667,735) is withdrawn for the reasons set forth above.

Applicant's arguments filed 11-28-2007 have been fully considered but they are not persuasive with respect to the disclosure of Buscemi et al. Claim 1 recites "polymerizable alkoxyated (meth)acrylate". Buscemi et al specifically disclose alkoxyated di(meth)acrylates, such as triethylene glycol di(meth)acrylate, tetraethylene glycol di(meth)acrylate and polyethylene glycol di(meth)acrylate, as being equivalent to neopentyl glycol diacrylate (used in the Examples and discussed in applicant's remarks) in the disclosed compositions (column 2, line 56, to column 3, line 3). Thus compositions taught by Buscemi et al comprising an alkoxyated di(meth)acrylate anticipate the instantly claimed compositions and applicant's arguments are not found persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 recites a photoinitiator is an acrylated amine synergists are set forth in a Markush group of "photoinitiators", however, acrylated amine synergists are not known to function as photoinitiators.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12, 16, 17, 21-23, 27-32, 34-37 and 41 are rejected under 35 U.S.C. 102(b) as anticipated by Buscemi et al (5,693,034). Buscemi et al disclose a lubricious polymer network comprising the reaction product of a vinyl prepolymer and an uncrosslinked hydrogel retained within the reaction product so that the network exhibits greater lubricity when wet. The hydrogels disclosed include polyethylene oxide (column 2, lines 34-41). The vinyl monomers include glyceryl propoxy triacrylate and diacrylates such as di-, tri-, tetra- or poly-ethylene glycol di(meth)acrylates (column 2, lines 56, to column 3, line 3). Isopropyl alcohol and water can be used as solvent (column 3, lines 4-11). A free radical initiator, such as azobisisobutyronitrile, is employed and curing can be by UV light exposure (column 3, lines 12-13 and lines 32-43). UV curing in the presence of azobisisobutyronitrile is taught in the examples. See Examples 1, 4 and 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 11, 13, 15, 24, 25, 33, 37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al (5,693,034), as applied to claims 1-9, 12, 16, 17, 21-23, 27-32, 34-37 and 41 above, and further in view of Bae et al (5,667,735). Buscemi et al disclose vinyl monomers including glyceryl propoxy triacrylate and diacrylates such as di-, tri-, tetra- or poly-ethylene glycol di(meth)acrylates (column 2, lines 56, to column 3, line 3). A free radical initiator, such as azobisisobutyronitrile, is employed and curing can be by UV light exposure (column 3; lines 12-13 and lines 32-43).

Bae et al disclose coatings for ophthalmic devices. The compositions comprise polyacryloylated alkane polyols, alkoxyated alkane polyols having at least three acrylate groups, such as ethoxylated trimethylolpropane triacrylate, a photoinitiator and other additives (column 3, lines 37-57, and column 5, lines 19-42). The photoinitiators taught include Darocure 1173, Irgacure 500 and Irgacure 907 (2-methyl-1-[4-(methylthio)phenyl]-2-morpholino-propanone-1) (column 5, lines 43-50). Additional photoinitiators, including azobisisobutyronitrile, are taught in column 11, lines 18-39.

With respect to claims 10, 11 and 33, It would have been obvious to one skilled in the art at the time of the invention to employ an alkoxyated alkane polyols having at least three acrylate

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groups, such as ethoxylated trimethylolpropane triacrylate, as the alkoxylated (meth)acrylate in the compositions disclosed by Buscemi et al. Buscemi et al provide motivation by teaching that vinyl monomers such as glyceryl propoxy triacrylate can be employed as well as the disclosed alkoxylated di(meth)acrylates. Bae et al provide motivation by using ethoxylated trimethylolpropane triacrylate in the examples. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of providing an effective crosslinking monomer in the compositions disclosed by Buscemi et al.

With respect to claims 24, 25 and 40, It would have been obvious to one skilled in the art at the time of the invention to employ one or more of the additives taught by Bae et al in analogous compositions in the compositions disclosed by Buscemi et al. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of modifying the composition as desired by addition of the conventional additives taught by Bae et al.

With respect to claims 13, 15, 37 and 39, It would have been obvious to one skilled in the art at the time of the invention to employ any one of the photoinitiators corresponding to those set forth in instant claims 13, 15, 33 and 39, such as 2-methyl-1-[4-(methylthio)phenyl]-2-morpholino-propanone-1, disclosed by Bae et al for the azobisisobutyronitrile initiator in the UV curable compositions disclosed by Buscemi et al. Buscemi et al provide motivation by disclosing that the disclosed composition are UV light curable. Bae et al provide motivation by disclosing various photoinitiators, including a morpholino propanone photoinitiator, useful for polymerizing alkoxylated (meth)acrylate monomers analogous to the polymerizable monomers taught by Buscemi et al. One skilled in the art at the time of the invention would have been

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motivated by a reasonable expectation of providing a suitable photoinitiator for the compositions disclosed by Buscemi et al.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al (5,693,034) in view of Bae et al, as applied to claims 1-13, 15-17, 21-24, 27-37 and 39-41 above, and further in view of Wang et al (6,458,867). Buscemi et al disclose compositions comprising difunctional reactive diluents comprise alkoxyated (meth)acrylates (columns 2-3). Bae et al disclose analogous compositions and teach conventional additives, such as adhesion promoters, therefor.

Wang et al disclose hydrophilic lubricant coatings for medical devices. The hydrophilic coatings are obtained from a nonhydrophilic polymeric material converted to a carboxylic acid or alcohol (column 8, lines 47-52, and column 9, lines 20-67, and column 15, lines 13-34). Polyalkylene glycols are preferred. A crosslinkable primer composition comprising compounds having hydrophilic functionality, such as an amino silane, is taught (column 11, line 47, to column 12, line 28).

It would have been obvious to one skilled in the art at the time of the invention to include a compound such as the amino silane taught by Wang et al in the compositions disclosed by Buscemi et al in order to take advantage of the coupling properties of the silane compound. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of improving the adhesion of the coating composition to the substrate being coated.

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Claims 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al (5,693,034) in view of Bae et al, as applied to claims 1-13, 15-17, 21-24, 27-37 and 39-41 above; and further in view of Kapoor et al (WO 03/046119). Neither Buscemi et al nor Bae et al teaches acrylated amine synergists employed with the photoinitiators in the disclosed compositions. Kapoor et al disclose radiation curable detergent compositions and teach using acrylated amine synergists to promote curing by generation of free radicals and by overcoming oxygen inhibition at the coating surface. See page 7, line 24, to page 8, line 11, page 11, line 19, to page 12, line 13, page 14, line 19, to page 15, line 30.

It would have been obvious to one skilled in the art at the time of the invention to include an acrylated amine synergist in the UV light curable composition comprising a free radical photoinitiator taught by Buscemi et al in combination with Bae et al. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of promoting curing by generation of free radicals and by overcoming oxygen inhibition at the coating surface, as taught by Kapoor et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
1/17/2008

/Susan W Berman/
Primary Examiner
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